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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,480	05/19/2000	Gregory A Kopia	CRD-850	1106

7590 10/21/2002

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EXAMINER	
FERKO, KATHRYN P	
ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/575,480	Applicant(s) KOPIA ET AL.	
	Examiner Kathryn Ferko	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *12-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5-6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-11 and 15 in Paper No. 8 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 1 recites the limitation "the treatment," "the intravascular," and "the surface" in lines 1 and 2. Claim 2 recites the limitation "the group" in lines 2. Claim 5 recites the limitation "the ras inhibitor" in lines 1 and 2. Claim 7 recites the limitation "the group" in line 2.

There is insufficient antecedent basis for these limitations in the claims.

3. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites "said exhibitor." However, no prior mention is made to an exhibitor. Claim 15 depends from claim 8, which recites an inhibitor. Therefore, the scope and intent of the claim is unclear. Any art rejections are as best understood.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris et al. in US Patent No. 5,516,781.

Morris et al. disclose a process for the treatment of restenosis via intravascular infusion or delivery by release from a surface of a stent of combinations of at least two drugs to a patient in therapeutic dosage amounts; and a combination of agents that includes an anti-inflammatory agent, wherein Cyclosporin A is known to have anti-inflammatory effects, and an antiproliferative agent, as recited in column 4 and claims 1-5.

6. Claims 1-4 are rejected under 35 U.S.C. 102(a or e) as being anticipated by Ragheb et al. in US Patent No. 6,299,604.

Ragheb et al. disclose a process for the treatment of restenosis via intravascular infusion or delivery by release from a surface of a stent of

combinations of at least two drugs to a patient in therapeutic dosage amounts; and a combination of agents that includes an anti-inflammatory agent and an antiproliferative, as recited in column 2, lines 40-67, column 3, lines 54-67, column 4, column 7, lines 62-67, column 8, and column 9; an anti-inflammatory agent that is dexamethasone and an anti-proliferative that is taxol, as recited in column 9, lines 45-55; and a combination of a growth factor and an anti-proliferative, as recited in column 9, lines 50-60 and column 21, lines 45-55, and column 4, lines 55-60, wherein any combination of bioactive materials can be employed.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604 in view of End.

Ragheb et al. disclose the invention as applied to claims 1 and 2. However, Ragheb et al. do not explicitly recite R11577. On the other hand, End teaches the ras inhibitor, R11577. Therefore, it would be obvious to one with ordinary skill in the art modify the invention of Ragheb et al. to include R115777 as a signal transduction inhibitor for the purpose of increasing antiproliferation.

9. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604 in view of Levitzki et al. in US Patent No. 5,932,580.

Ragheb et al. disclose the invention as applied to claim 1. However, Ragheb et al. do not explicitly recite tyrphostin as a tyrosine inhibitor. However, Levitzki et al. teach of tyrphostin, as recited in column 5, lines 35-67, column 6, and column 8. Therefore, since implantation is a method of administration as recited in column 8, line 67, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Ragheb et al. to include a the tyrosine inhibitor of tyrphostin to suppress SMC.

10. Claims 8-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604 in view of Nagler et al. in US Patent No. 6,159,488.

Ragheb et al. disclose the invention as applied to claims 1-4. However, Ragheb et al. do not explicitly recite halofuginone as an inhibitor of extracellular matrix. On the other hand, Nagler et al. teach a stent coated with halofuginone, as recited in column 9 and column 10. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the system of Ragheb et al. to include halofuginone for the purpose of inhibiting SMC proliferation.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-11 and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 and 25 of copending Application No. 09/850,482. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for identical subject matter. In some aspects some limitations are broader while others are more specific.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 5,519,042; US Patent No. 6,369,039; US Patent No. 5,569,462; US Patent No. 6,316,018; US Patent No. 6,225,346; US Patent No. 5,665,728; US Patent No. 5,916,910; US Patent No. 6,287,628; US Patent No. 6,284,305; US Patent No. 6,403,635; US Patent No. 6,193,746; US Patent No. 6,379,382; US Patent No. 6,387,121; and US 2002/0095114;

US 2002/0082685; US 2002/0061326; US 2002/0010418; US 2002/0133224; US 2002/0133222; US 2002/0127327; US 2002/0123505; US 2002/0119178; US 2002/0203526; US 2002/0099438; and US 2002/0082680.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF
October 1, 2002

Henry Bennett
Supervisory Patent Examiner
Group 3700